

PART III: CONSUMER INFORMATION

Pr APO-DILTIAZ SR
Diltiazem HCl Sustained Release
(Twice-a-day) Capsules Apotex Standard
60, 90 and 120 mg

Read this carefully before you start taking APO-DILTIAZ SR and each time you get a refill. This leaflet is a summary and will not tell you everything about APO-DILTIAZ SR. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about APO-DILTIAZ SR

ABOUT THIS MEDICATION

What the medication is used for:

APO-DILTIAZ SR is used for:

- the management of effort associated **angina** (chest pain)
- the treatment of mild to moderate **high blood pressure**.

APO-DILTIAZ SR should normally be used in those patients in whom treatment with other blood pressure reduction medications has been ineffective, or have been associated with unacceptable side effects.

What it does:

APO-DILTIAZ SR belongs to the group of drugs called “calcium channel blockers” or “calcium antagonists”.

APO-DILTIAZ SR relaxes the arteries, thereby lowering blood pressure.

APO-DILTIAZ SR reduces the amount of oxygen that your heart muscle needs. This helps control chest pain.

When it should not be used:

Do not use APO-DILTIAZ SR if:

- You are pregnant or plan to become pregnant.
- You are breastfeeding.
- You have a known allergy to diltiazem or to any of the non-medicinal ingredients.
- You have very low blood pressure (< 90 mmHg systolic).
- You have heart rhythm disorders in the absence of a pacemaker.
- You have severe heart failure with fluid in the lungs.
- You are taking a medicine called dantrolene used for severe muscle spasms or severe fever.
- You are using ivabradine

What the medicinal ingredient is:

Diltiazem Hydrochloride

What the non-medicinal ingredients are:

Eudragit, methylcellulose, microcrystalline cellulose, polysorbate 80, talc and tributyl citrate. The capsule shell contains the non-medicinal ingredients gelatin, titanium dioxide, FD&C blue #1, FD&C red #40, FD&C yellow #6 and D&C yellow #10.

What dosage forms it comes in:

Capsules: 60, 90 and 120 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use APO-DILTIAZ SR talk to your doctor or pharmacist if:

- You have very low blood pressure.
- You have ever had a bad or unusual reaction to any drug containing diltiazem in the past.
- You have heart, liver, or kidney disease.
- You have high blood sugar or diabetes.
- You are 65 years or older.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

Additional monitoring of your dose or condition may be needed if you are taking other drugs.

The following may interact with APO-DILTIAZ SR:

- Antifungal medications with a name ending in azole;
- Medications used to control the immune system such as cyclosporine;
- Certain antibiotics should not be taken with APO-DILTIAZ SR such as erythromycin, rifampin. Check with your pharmacist if not sure;
- Sleeping pills such as benzodiazepines (midazolam, triazolam);
- Other blood pressure medications: alpha antagonists, beta-blockers;
- Heart medications: Amiodarone, digoxin, digitalis, flecainide, nifedipine, propafenone, quinidine, verapamil; ivabradine
- anaesthetics;
- Lithium and imipramine used for some types of mental illness;
- Drugs that dilate the blood vessels: short and long acting nitrates;
- Medications used to control seizures:
- carbamazepine, phenobarbital, phenytoin;
- Warfarin used as anticoagulant;
- Cholesterol lowering medications: statins;
- Theophylline used for breathing problems;
- Terfenadine or ranitidine used for allergies;

IMPORTANT: PLEASE READ

- Medications used to control stomach ulcers such as cimetidine will increase the effects of APO-DILTIAZ SR;
- Multivitamins with minerals (calcium-containing products);
- Drugs to treat inflammation: corticosteroids, methylprednisolone;
- Dantrolene used for severe muscle spasms or severe fever.
- Acetylsalicylic acid (Aspirin) or antiplatelet drugs such as ticagrelor, cilostazol, clopidogrel, dipyridamole, ticlopidine.
- X-Ray contrast agents.

Alcohol may cause low blood pressure and dizziness when you go from lying or sitting to standing up. This can especially occur after the first dose and when the dose is increased. Tell your doctor if you experience dizziness, light-headedness, fainting, decreased blood pressure or increased heart rate.

Grapefruit juice when consumed too often while taking APO-DILTIAZ SR may cause headache, irregular heartbeat, edema (swelling), unexplained weight gain, and chest pain. Tell your doctor if this happens to you. Your doctor may recommend that grapefruit juice be avoided if this happens to you.

PROPER USE OF THIS MEDICATION

-Do not miss doses or take extra doses, unless your doctor tells you. If you are not clear about the directions, ask your doctor or pharmacist.

Take APO-DILTIAZ SR exactly as your doctor tells you. APO-DILTIAZ SR is taken once a day. Dosage should be individualised.

Swallow capsules whole. DO NOT chew or crush APO-DILTIAZ SR capsules.

Usual Adult Dose:

Angina
120 to 360 mg/day. **Initiation of treatment and individual titration of dosage should be carried out using the conventional tablets.** Always follow your doctor's instructions.

High blood pressure

Usual dose: 120 to 360 mg per day administered in two equally divided doses.
Maximum dose: 360 mg a day.

Overdose:

In case of drug overdose, contact a health care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Headache, dizziness, malaise; Nausea (feeling like vomiting);
- Flushing (facial redness) or feeling unusually warm;
- Unusual tiredness and weakness;
- Upset stomach.

APO-DILTIAZ SR can cause abnormal blood results. Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS. HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Low Blood Pressure: dizziness, fainting, light-headedness May occur when you go from lying or sitting to standing up		√	
	Fast, slow, or irregular heartbeat		√	
	Peripheral edema: swelling of the ankles	√		
	Respiratory tract infection: pharyngitis, rhinitis		√	
	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
Uncommon	Depression: low mood, lack of interest in usual activities, change in sleep and appetite.	√		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Heart block: A disease in the electrical system of the heart causing lightheaded ness, fainting and irregular heartbeat.			√
Heart Attack: shortness of breath, chest pain			√
Angina: Chest pain		√	
Heart Failure: shortness of breath, leg swelling, and exercise intolerance		√	
Eye Problems: decreased vision, irritation, sore red eyes	√		
Increased blood sugar: frequent urination, thirst, and hunger	√		
Rare			
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	
Unknown			
Serious Skin Reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, hypersensitivity Syndrome): any combination of itchy skin rash, redness, blistering and peeling of the skin and /or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain, yellowing of the skin or eyes, dark urine.			√

This is not a complete list of side effects. For any unexpected effects while taking APO-DILTIAZ SR, contact your doctor or pharmacist

HOW TO STORE IT

Store at room temperature 15°C to 30°C. Protect unit dose packages from humidity and light. **Keep out of sight and reach of children.**

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about APO-DILTIAZ SR:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this patient medication information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer’s website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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